[0026] The orthosis of the present invention is designed to compensate for weakness, pain, and/or decreased range of motion (either alone or in combination) at the ankle that result from a variety of potential diagnoses including, but not limited to, ankle fusion, talus or calcaneus fractures, tibial nerve injuries, peroneal nerve injuries, partial foot amputation (which results in ankle plantarflexion weakness), soft tissue loss in the leg (resulting in inherent weakness), or pain in the ankle during weight bearing activities.

[0027] Current research suggests that the orthosis of the present invention not only compensates for weakness, but also generates forces about the ankle that more closely approaches the normal gait than other currently available orthoses. The article Patzowski et al., *Comparative Effect of Orthosis Design on Functional Performance*, J. Bone Joint Surg. Ab., 2012; 94:507-15, is incorporated by reference herein in its entirety. The article Patzowski et al., *Can an Ankle-Foot Orthosis Change Hearts and Minds*?", J. Surgical Orthopaedic Advances, 20(1):8-18, 2011, is also incorporated by reference herein in its entirety.

[0028] In specific embodiments, the orthosis of the present invention may be applied to the leg below the knee. The orthosis (also referred to as the Intrepid Dynamic Exoskeletal Orthosis or IDEO) may comprise the following components (description from the upper/proximal aspect to the lower/distal aspect).

A. Proximal Cuff

[0029] With reference now to FIG. **1**, the exoskeletal orthosis **100** according to the present invention comprises a proximal cuff **110**. The proximal cuff may comprise at least one of a carbon material, reinforced carbon fiber composition, or resin material. The cuff may have a bivalve or a monolithic configuration.

[0030] A monolithic, one-piece, solid configuration comprises a solid cuff and is designed for a patient who has a stable size of the upper leg (calf and shin) and does not have limited ankle plantarflexion.

[0031] A bivalve cuff comprises a hinge **115** (as shown in FIGS. **2-3**) along an upper edge or aspect, thereby allowing the proximal cuff **110** to have a wider opening distally when donning the brace. This configuration may be utilized for patients who are not able to plantarflex the ankle enough to fit through a monolithic (solid) configuration and also allows for volume fluctuation of the upper leg. The hinge allows the proximal cuff to open upward due to a proximal fixed axis point.

[0032] In one or more embodiments, the proximal cuff **100** may have a strap **120** to help hold it in place while in use.

B. Posterior Strut

[0033] The exoskeletal orthosis **100** comprises at least one posterior strut **130** for connecting the proximal cuff **110** to an ankle/footplate section **140**. The at least one posterior strut **130** may comprise a single bar or dual bars (as shown in FIG. **3**), which may be bonded together. The at least one posterior strut may be of any shape for example, a flat bar, a cylindrical or tubular shape, or having a circular or semi-circular cross section. In one or more embodiments, the at least on posterior strut **130** may have a length of about 5 inches to about 12 inches.

[0034] In specific embodiments, the at least one posterior strut **130** may comprise an alignable dynamic carbon strut, for example, a TRULIFE Littig strut or a MEDI CLEVER BONE™ strut. The Littig strut was originally designed for use in the upper portion of hip disarticulation prostheses. The MEDI CLEVER BONE™ strut (bone system) may be designed for use as a dynamic pylon for transtibial prostheses.

[0035] The at least on posterior strut **130** may comprise at least one of a carbon material, reinforced carbon fiber composition, or resin material. In a specific embodiment, the at least one posterior strut may have an Aileron core.

[0036] In one or more embodiments, the at least on posterior strut may comprise an SLS material. Selective laser sintering (SLS) is an additive manufacturing technique that uses a high power laser (for example, a carbon dioxide laser) to fuse small particles of plastic, metal (direct metal laser sintering), ceramic, or glass powders into a mass that has a desired 3-dimensional shape.

C. Mounting Plates

[0037] The exoskeletal orthosis **100** may comprise at least one mounting plate, for example, two mounting plates: a first mounting plate **150** for attaching one end of the at least one posterior strut **130** to the proximal cuff and a second mounting plate **160** for attaching an opposite end of the at least one posterior strut **130** to the ankle section/footplate **140** (as shown in FIGS. **1** and **4**). In one or more embodiments, the at least one mounting plate comprises an ÖSSUR® posterior mounting plate (designed for transtibial prostheses).

[0038] The mounting plates **150**, **160** may include a fastener including, but not limited to, at least one of a screw, bolt, nail, nut, adhesive, combination thereof, or any other effective fastener.

[0039] The attachment of the at least one posterior strut **130** to an ankle section/footplate **140** may be slightly more proximal than traditional orthoses. This helps offset motion within the ankle, which is often painful or severely limited in these patients, to the at least one posterior strut without compromising comfort.

D. Ankle Section/Footplate

[0040] The exoskeletal orthosis **100** comprises an ankle section/footplate **140**. The ankle section/footplate comprises a supramalleolar ankle section **170** and footplate section **180**. The ankle section/footplate **140** may be a single piece comprising a reinforced carbon fiber composition. In one or more embodiments, the ankle section **170** comprises a lateral wing **190** for mediolateral stability and for fitting better in shoes or boots (FIG. **5**). In one or more embodiments, the ankle section may also have a medial wing.

[0041] In one or more embodiments, the footplate section **180** has a "rollover" shape. The shape of the footplate section **180** positions an individual's toes in slight extension and extends to his or her toetips. A forefoot (end of the footplate) is set in slight plantarflexion compared to a midfoot. In one or more embodiments, the ankle section/footplate **140** may be stiff due to the layering of materials and carbon fiber. The footplate section **180** may have an arch (instead of being completely flat) and have extension at the metatarsophalangeal joints, which enables the metatarsal heads to remain in contact with the ground for a longer duration during ambulation.

[0042] The plantar surface of the footplate allows optimal function of the at least one posterior strut and long-term durability of the orthosis. As noted, the footplate section may